IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327 MDL No. 2327**
THIS DOCUMENT RELATES TO *All Ethicon Wave 11 cases listed in Exhibit A to the Motion*	**JOSEPH R. GOODWIN U.S. DISTRICT JUDGE**

MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO LIMIT THE OPINIONS AND TESTIMONY OF DEFENSE EXPERT LAWRENCE LIND, M.D.

Plaintiffs respectfully request that the Court limit the opinions and testimony proffered by Defendants' expert Lawrence Lind, M.D. ("Dr. Lind"), pursuant to Federal Rule of Evidence 702. In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Lind is the co-chief of the Division of Urogynecology and Pelvic Reconstructive Surgery at North Shore University Hospital and Long Island Jewish Medical Center, and Medical Director of the Sharon Joyce Schlanger Center for Women's Care. (*See* Exhibit C (Expert Report); Exhibit D (Curriculum Vitae)). He is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. (*See id.*). Dr. Lind obtained his medical degree from Cornell University Medical College, New York, NY. (Ex. D at 1).

Defendants have asked Dr. Lind to provide general expert opinions on the TVT, TVT-O, TVT-Exact, and TVT-Abbrevo. In his deposition, Dr. Lind admitted the following:

- None of the articles included in his bibliography address any of the TVT sling products. (Exhibit B, Rough Draft Transcript of Deposition of Dr. Lawrence Lind, at 78:4-8).[1]

- He has not written a peer-reviewed journal article on any of the TVT products. (*Id.* at 82:20-24 – 83:1-8).

- He has never been directly involved with a published study of any kind related to TVT products. (*Id.* at 78:9-13).

- The opinions he is providing in this litigation have never been published in any peer-reviewed journal. (*Id.* at 134:10-14).

- He has never been involved in any comparative trials or randomized controlled trial involving transvaginal mesh treatment of stress urinary incontinence. (*Id.* at 134:15-24).

- He only uses Ethicon TVT slings in 10 percent of his practice. (*Id.* at 266:10-12).

- He preferred to use competitors' products over Ethicon's TVT products in his own practice, even when he was under contract with Ethicon. (*Id.* at 326:6-11).

Moreover, Dr. Lind considers himself to be an expert in a very wide range of fields:

- He considers himself an expert in chemical engineering, even though he has no education or work experience as a chemical engineer. (*Id.* at 87:17-19; 90:7-18).

- He considers himself an expert in pathology, based upon his review of literature related to pathologic specimens of mesh and sling material, even though he does not actually review histopathologic slides as part of his medical practice, and even though he only reviews reports that come to him from pathologists. (*Id.* at 92:23-24; 93:1-10; 20-24; 94:1-3).

- He considers himself an expert in polymer chemistry, based upon his practice as a medical doctor, despite having no educational training related to chemistry or engineering. (*Id.* at 96:4-24; 97:1-24; 98:1-10).

- He considers himself an expert in biomaterials, based upon his practice as a medical doctor, despite having no educational training related to biomaterials. (*Id.* at 98:17-23).

- He considers himself an FDA expert as it relates to instructions for use for mesh products, based upon his review of materials in preparing to be a litigation expert. (*Id.* at 99:16-24; 100:1-22; 101:1-24; 102:1-4, 16-24; 103:1-24; 104:1-3).

[1] Dr. Lind's deposition was conducted on August 7, 2019, only eight days before the filing deadline. Thus, only a rough draft transcript is available at this time.

- He considers himself an expert on warnings, even though he has not himself drafted any instructions for use for any medical device. (*Id.* at 104:4-7, 20-22; 105:1-5; 106:8-10; 107:18-22).

- He considers himself an expert on the design of medical devices, even though he has never designed a transvaginal mesh product that has been funded or produced and holds no patents on any medical devices. (*Id.* at 118:3-24; 119:1-12; 125:12-15).

Finally, Dr. Lind testified as to his own practice that he does not have a formal tracking method for patient outcomes:

- He does not have any kind of internal registry tracking of patients to see what complications they've had over a long-term period. (*Id.* at 207:24; 208:1-4).

- He does not record or collect information on complication rates or patients who are lost to follow-up. (*Id.* at 208:12-23).

- He does not track the complication rates in patients with regard to specific mesh products. (*Id.* at 210:8-20).

- He does not have a tracking system in place for patients with regard to whether mechanical or laser cut mesh was used. (*Id.* at 211:18-23).

As discussed further below, Dr. Lind's opinions regarding Defendant's TVT devices should be excluded or limited because he does not have the requisite expertise as to TVT devices, because he is alarmingly overconfident with respect to his fields of expertise, and because any complication rates in his own practice are not documented and unreliable.

LEGAL STANDARD

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified ... by knowledge, skill, experience, training, or education," and if his testimony is

(1) helpful to the trier of fact in understanding the evidence or determining a fact in issue;
(2) "based upon sufficient facts or data"; and
(3) "the product of reliable principles and methods" that
(4) have been reliably applied "to the facts of the case."

Fed. R. Evid. 702. In the context of Rule 702, "'knowledge connotes more than subjective belief or unsupported speculation." *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 509 U.S. 579, 590 (1993).

If the expert is qualified, the U.S. Supreme Court has established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admissible if it "rests on a reliable foundation and is relevant.'" *Tyree v. Boston Scientific Corp*., 54 F.Supp.3d 501, 516 (S.D. W. Va. 2014) (*quoting Daubert*, 509 U.S. at 597). Although "[t]he proponent of expert testimony does not have the burden to 'prove' anything to the court," he or she must nonetheless "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id*. (*quoting Md. Cas. Co. v. Therm-O-Disc, Inc*., 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided factors for the court to consider in applying F.R.E. 702:

> (1) whether a theory or technique can be or has been tested;
>
> (2) whether it has been subjected to peer review and publication;
>
> (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and
>
> (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.

Cooper v. Smith & Nephew, Inc., 259 F.3d 194, 199 (4th Cir. 2001) (*citing Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). As the gatekeeper, the district court serves in an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc*., 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999), and *Daubert*, 509 U.S. at 588, 595).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

ARGUMENT

I. Dr. Lind is Alarmingly Overconfident With Respect to His Fields of Expertise, and Any Opinions Outside of his Specialized Field Are Unreliable and Should be Excluded.

While someone may be an expert in one field, that does not mean he or she is an expert in everything. Yet, Dr. Lind has testified in his deposition that he believes he is an expert in at least 10 fields.

Daubert and its progeny have made clear that expert opinions must be limited to the expert witnesses's area of expertise. *See Mohney v. USA Hockey, Inc.*, 300 F. Supp. 2d 556, 564 (N.D. Ohio 2004) ("A court should exclude proffered expert testimony if the subject of the testimony lies outside the witnesses's area of expertise. In other words, a party cannot qualify as an expert generally by showing that the expert has specialized knowledge and training which would qualify him or her to opine on some other issue.") (citing 4 Weinstein's Fed. Evid. § 702.06[1], at 702-52 (2000)); *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D.N.C. 2007) (Trial courts must ensure that a purported expert witness "is not merely parroting the opinions of others, but that the matters upon which she will opine are clearly within her area of expertise.")). "In other words, a party cannot qualify as an expert generally by showing that the expert has specialized knowledge or training which would qualify him or her to opine on some other issue." *Redman v. John D. Brush & Co.*, 111 F.3d 1174, 1179 (4th Cir. 1997).

On remand in *Daubert v. Merrell Dow Pharmaceuticals, Inc*., 43 F.3d 1311, 1315 (9th Cir) ("Daubert II"), the Ninth Circuit recognized that for an expert to testify, it is established that the proffered witness **is an expert in a particular scientific field**. An expert must be qualified in the particular field that relates to the substance of the anticipated testimony:

> A witness must be qualified in the specific subject for which his testimony is offered. Just as a lawyer is not by general education and experience qualified to give an expert opinion on every subject of the law, so too a scientist or medical doctor is not presumed to have expert knowledge about every conceivable scientific principle or disease.

Whiting v. Baston Edison Co., 891 F. Supp. 12, 24 (D. Mass. 1995). "The trial court's gatekeeping function requires more than simply 'taking the expert's word for it.'" Advisory Committee Notes on Fed. R. Evid. 702, 2000 Amendments (citing *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1319 (9th Cir. 1995) ("We've been presented with only the experts' qualifications, their conclusions and their assurances of reliability. Under *Daubert*, that's not enough.").[2] Where the witness is relying solely or primarily on experience, rather than education or training, "then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *Id. See also Kumho Tire Co. v. Carmichael*, 119 S. Ct. 1167, 1176 (1999) ("[I]t will at times be useful to ask even of a witness whose expertise is based purely on experience … whether his preparation is of a kind that others in the field would recognize as acceptable.")

[2] This Court has previously noted that "the Fourth Circuit appears more willing to 'take the expert's word for it' so long as the expert **has demonstrated that he or she has experience in a field writ large**." *Griffin v. Bos. Sci. Corp*., No. 2:13-cv-11876, 2016 WL 3031700 (S.D. W. Va. May 25, 2016) (emphasis added); (citing *Eskridge v. Pac. Cycle, Inc.*, 556 F. App'x 182, 190-91 (4th Cir. 2014) (unpublished) (finding a bicycle engineer's experience with "hundreds of cases of accidents" and "decades of experience in the industry in general" provided a reliable basis to testify about whether bicycle purchasers read warnings and dismissing concerns that the bicycle expert's testimony was nothing more than personal opinion because of his "years of experience" and assurance that all of his opinions were "to a reasonable degree of engineering certainty")).

Dr. Lind's deposition makes clear that he is overconfident in his knowledge and overreaching with respect to his fields of expertise. As stated above, in addition to the fields of Obstetrics and Gynecology, he considers himself an expert in the following fields:

- Chemical Engineering;
- Pathology;
- Polymer Chemistry;
- Biomaterials;
- FDA Regulations as it relates to IFUs;
- IFUs and Warning Labels; and
- Medical Device Design.

Even though Dr. Lind may be well-credentialed in his fields of obstetrics, gynecology, and female pelvic medicine and reconstructive surgery, that does not give him free rein to testify about any related field. For example, in *In re Gadolinium-Based Contrast Agents Products Liability Litigation*, 2013 WL 587655 (N.D. Ohio Feb. 13, 2013), hundreds of people alleged harm from exposure to gadolinium-based contrast agents used during MRI exams. The defendant manufacturer's expert witness held a Bachelor of Science in Chemistry, a Doctorate in Coordination and Bioinorganic Chemistry, and a Master's of Business Administration. *Id* at *9. However, the expert offered opinions on a broad range of topics, including toxicology, clinical studies, and pharmacology. *Id.* The court significantly limited the expert's testimony, precluding him from opining on areas outside of his trained field of bioinorganic chemistry. *Id.* at *11.

Dr. Lind bases his expertise in each of the areas listed above essentially upon his general experience as a medical doctor, review of literature for litigation, and minimal participation in a single study. (*See* Ex. B at 87-107). In his deposition testimony, he offered very little support or detail for his statements regarding his "expertise" in so many fields. It is a stretch to believe that professionals in the fields of chemical engineering, pathology, polymer chemistry, biomaterials, FDA regulations, and medical device design would agree that this is sufficient. If the Court allows Dr. Lind to testify at trial, Plaintiffs request that the Court limit his testimony to those fields for

which he has the proper education and experience—obstetrics, gynecology, and female pelvic medicine and reconstructive surgery.

II. Dr. Lind's Complication Rates in His Own Practice are Unreliable, and Any Opinions Regarding His Complication Rates Should Be Excluded.

Dr. Lind has not collected patient data and organized it or recorded it with respect to efficacy or safety, or complication rates; he has not compiled any kind of long-term spreadsheet with data to track complications; he does not track information with respect to specific mesh products; nor does he track whether specific types of mesh are used. Yet, he somehow asserts that he knows his complication rates by simply following up with patients and thus, "knows" how they're doing. (*See* Ex. B at 203-11). Plaintiffs move to exclude Dr. Lind's opinions about any complication rates in his own practice, and any other "rates" he claims to give from his own practice, because he does nothing to formally track such information.

Testimony by an expert witness must be "based upon sufficient facts or data" and be "the product of reliable principles and methods." Fed. R. Evid. 702. For expert testimony to be reliable, the opinion must be "based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using a scientific or other valid methods." *Oglesby v. Gen. Motors Corp.*, 190 F.3d 244, 250 (4th Cir. 1999). "Red flags that caution against certifying an expert include reliance on anecdotal evidence… ." *Newell Rubbermaid, Inc. v. Raymond Corp.*, 676 F.3d 521, 527 (6th Cir. 2012). Notably, this Court has previously excluded unreliable expert testimony on complication rates associated with a mesh device. *See Eghnayem v. Bos. Sci. Corp*., 57 F. Supp. 3d 658, 677 (S.D.W. Va. 2014); *Sanchez v. Bos. Sci. Corp*., No. 2:12-CV-05762, 2014 WL 4851989, at *14 (S.D.W. Va. Sept. 29, 2014) (finding that a plaintiff expert's testimony "giving the benefit of the doubt" to the patient and opining as to a higher complication rate "is not a scientific basis for determining the complication

rates associated with a mesh device."). A reliable expert would not "make sweeping statements without support … ." *Sanchez*, 2014 WL 4851989, at *11.

In short, Dr. Lind's methods of identifying and tracking the complications at issue in his own practice are not sufficient or scientifically sound because there is no actual data available to verify his supposed complication rates, and any testimony regarding speculative complication rates or any other unsupported rates from his own practice should be excluded.

CONCLUSION

For the reasons stated above, Plaintiffs respectfully request that the Court grant their motion and limit the opinions and testimony of Defendants' expert Lawrence Lind, M.D. Plaintiffs further request any other and further relief that the Court deems just and equitable.

Dated: August 15, 2019

Respectfully submitted,

/s/Thomas P. Cartmell
Thomas P. Cartmell, Esq.
Jeffrey M. Kuntz, Esp.
Wagstaff & Cartmell LLP
4740 Grand Avenue, Suite 300
Kansas City, MO 64112
816-701-1102
Fax 816-531-2372
tcartmell@wcllp.com
jkuntz@wcllp.com

/s/ D. Renee Baggett
Bryan F. Aylstock, Esq.
Renee Baggett, Esq.
Aylstock, Witkin, Kreis and Overholtz, PLC
17 East Main Street, Suite 200
Pensacola, Florida 32563
(850) 202-1010
(850) 916-7449 (fax)
rbaggett@awkolaw.com
baylstock@awkolaw.com

Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that I filed the foregoing document on August 15, 2019, using the Court's CM-ECF filing system, thereby sending notice of the filing to all counsel of record in this matter.

/s/Thomas P. Cartmell
Attorney for Plaintiffs